UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JODI ROUVIERE and ANDRE ROUVIERE, *Plaintiffs*, v. DEPUY ORTHOPAEDICS, INC. n/k/a MEDICAL DEVICE BUSINESS SERVICES, INC. and HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS, *Defendants*.	)	Case No. 1:18-cv-04814-LJL-SDA

JOINT STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF HOWMEDICA OSTEONICS CORP.'S MOTION FOR SUMMARY JUDGMENT

Howmedica Osteonics Corp. ("HOC"), pursuant to Federal Rule of Civil Procedure 56(c), Local Rule 56.1 and Judge Liman's Individual Practices, and in support of its contemporaneously filed Motion for Summary Judgment, has met and conferred with Plaintiffs and states that the following material facts are not in genuine dispute and are submitted jointly:

1. In July 2009, Jodi Rouviere injured her right hip in a kitchen mishap. (Exh. A, Deposition of Jodi Rouviere ("JR Dep."), 68:21-69:12)

2. Over the next few years, Ms. Rouviere underwent multiple arthroscopic procedures on her hips. (*Id*., 75:21-25; 80:25-81:8; 84:1-5; *see also* ECF No. 227, Plaintiffs' Response to DePuy Statement of Material Facts, ¶3)

3. Shortly after her third arthroscopic procedure, Ms. Rouviere was given a likely diagnosis of Ehlers-Danlos Syndrome, a connective tissue disorder, by Deborah Barbouth, M.D.

(Exh. A, JR Dep., 85:16-86:20; 91:16-92:14; *see also* ECF No. 227, Plaintiffs' Response to DePuy Statement of Material Facts, ¶4).

4. After failure of conservative treatment, on August 14, 2012, Ms. Rouviere underwent a total right hip replacement surgery at the Hospital for Special Surgery in New York, performed by Dr. Robert Buly. (Exh. B, Aug. 14, 2012 Operative Report)

5. During that surgery, Dr. Buly implanted a DePuy titanium femoral stem and ceramic head, as well as a Stryker (i.e., HOC) MDM® liner and insert and acetabular cup. (*Id.*)

6. "The device caused injury upon implementation, physiological instability, toxicity, and toxic result over time." (Exh. C, Jodi Rouviere Interrogatory Responses, No. 9)

7. On multiple occasions in September 2012, Jodi Rouviere experienced "extreme dizziness and vertigo," as well as nausea and vomiting, and went to the Emergency Room on September 11, 2012 as a result of these symptoms. (Exh. D, Jodi Rouviere 11/23/20 Declaration, filed at ECF No. 233-19, ¶8; Exh. E, AR Declaration, filed at ECF No. 233-21, ¶9; Exh. M, Sandhouse Records, pp. 285-286)

8. In November of 2012, Ms. Rouviere complained to her osteopath of increasing right hip pain, as well as "searing, shooting pain down the right hip." (Exh. M, Sandhouse Records, pp. 269-270)

9. Plaintiffs allege in the Amended Complaint that "Post-operatively, Ms. Rouviere's "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System failed. [B]y by the beginning of 2013, she experienced pain and loss of range of motion." (ECF No. 26, Amended Complaint, ¶209)

10. At her deposition, when asked how her health was in the middle and later part of 2013, Ms. Rouviere testified that as 2013 progressed, her decline worsened, including more pain,

more instability and less function in her right hip. She also testified that during this timeframe, her heart would start beating harder and her body was tiring. (Exh. A, JR Dep., 135:8- 136:1)

11. In October 2013, Ms. Rouviere treated with a neurologist, Dr. Brad Herskowitz, complaining of headaches, heaviness in arms and legs, itching in her face and head, urinary urgency and hesitancy, and feeling like she has slowed down in general. (*Id*. at 141:4-24) She also continued to have hip pain at this time. (*Id*. at 142:4-7)

12. Treatment records from Ms. Rouviere's osteopath, Dr. Mark Sandhouse, from mid- to late 2013 reveal instability and pain in her right hip and displacement of the hip on multiple occasions. (Exh M, Sandhouse records: May 13, 2013 (displacement), May 29, 2013 (displacement); July 10, 2013 (right hip prosthesis bothering her, unstable and causing paresthesias down the right leg); July 17, 2013 (right hip externally rotated); August 19, 2013 (right femur out); September 11, 2013 (right hip feels out, "grinding"; right hip externally rotated); November 4, 2013 (right hip is "horrible"; pain radiates down past thigh))

13. In February 2014, Ms. Rouviere visited a neurologist, Dr. Simon Starosta-Rubenstein, because she was concerned with her "functional neurological decline." (Exh. C, JR Interrogatory Responses, No. 2, and attachment to Responses, p. 30)

14. On June 27, 2014, Ms. Rouviere complained to her physical therapist of, among other things, vertigo, dizziness and lightheadedness, blurred and double vision, vision flashes and halos, tinnitus, nausea and vomiting, shaking episodes, tremors, changes in appetite, changes in sleep patterns, poor coordination, numbness in her right leg, chronic pain, joint pain, muscle pain at rest, hoarseness, speech difficulty with pain, weakness in legs and arms, and heart palpitations. (Exh. N, Healy Physical Therapy records, pp. 2-5)

15. On May 17, 2015, Ms. Rouviere was admitted to Doctor's Hospital because of recurring episodes of instability of the right hip. The admission record notes that in addition to

right hip pain, for the previous eight months Ms. Rouviere had been "having problems with temperature regulation, tremors, blurred vision, cognitive impairment, dizziness and gaited instability." (Exh. O, Doctor's Hospital Records) Regarding this visit, Ms. Rouviere stated in a medical record exhibit filed with the Court: "My hip mispositions again. I cannot walk and am in excruciating pain. I am admitted to Doctor's Hospital (Coral Gables, FL) for 6 days of testing as I believe my unstable hip and neurological symptoms could be relational [sic] to metallosis." (Exh. P, "Jodi Rouviere Medical," filed at ECF No. 233-16, at 160)

16. In the Amended Complaint, Plaintiffs alleged that blood testing performed in May 2015 demonstrated "highly elevated Chromium level of 0.9 [mcg/L], Arsenic of [mcg/L] 5…Plaintiff has no source of exposure to chromium and cobalt and other metals that would account for her elevated blood levels of chromium or cobalt and other metals other than the subject product." (ECF No. 26, Amended Complaint, ¶¶210, 217)

17. [*See* HOC's Local Rule 56.1 Statement of Facts for this paragraph. Plaintiffs have *not* agreed to joint submission of Paragraph 17 of HOC's Local Rule 56.1 Statement of Facts.]

18. [*See* HOC's Local Rule 56.1 Statement of Facts for this paragraph. Plaintiffs have *not* agreed to joint submission of Paragraph 18 of HOC's Local Rule 56.1 Statement of Facts.]

19. On November 11, 2016, Ms. Rouviere underwent a partial revision surgery to remove and replace the MDM® liner and insert, as well as the DePuy femoral head. The revising surgeon, Dr. Alvarado, observed that the DePuy titanium stem had impinged upon the MDM cobalt chrome liner resulting in a notch in the neck of the titanium stem. He observed "a significant amount of grayish brown soft tissue consistent with metal debris," which he stated was indicative of "metallosis." (Exh. F, November 11, 2016 Operative Report; Exh. G, November 13, 2016 Discharge Summary; *see also* ECF No. 227, Plaintiffs' Response to DePuy Statement of Material Facts, ¶39)

20. Ms. Rouviere testified that after the revision surgery, Dr. Alvarado told her that she "was covered in metallosis" and that she had "pseudotumors consistent with damage to the tissue." (Exh. A, JR Dep., 168:10-22; 170:9-12)

21. Ms. Rouviere subsequently underwent two additional revision surgeries in February 2017 and May 2017, respectively, to remove and replace various components in her right hip. (*Id.*, 180:6-11; 189:14-18; 192:22-193:2)

22. Ultimately, in October 2017, at Ms. Rouviere's request, Dr. Alvarado performed a Girdlestone procedure in which all of the hip components were removed. (*Id.*, 203:1-5)

23. Among the injuries claimed by Ms. Rouviere in this action include physiological instability, pain, swelling, inflammation, adverse tissue reaction, necrosis, pseudotumor, metallosis, and toxicity resulting from metal debris generated by her hip components, as well as decreased mobility of the hip. (ECF No. 26, Amended Complaint, ¶¶127-128; Exh. C, JR Interrogatory Responses, No. 9; Exh. A, JR Dep., 168:10-22; 170:9-12)

24. Jodi Rouviere's disclosed experts identified local and systemic injuries that they opined were caused by metal debris released from her 2012 implants, including tissue damage and necrosis, metallosis, chronic fatigue, nausea, headaches, weakness, dizziness/vertigo, cognitive impairment, hip and other joint and muscle pain, tachycardia, dry eyes/blurred vision, and other immunological and neurological symptoms. (Exh. H, Tervaert Expert Report, pp. 3, 5-7, 11; Exh. L, Tervaert Dep., 89:18- 91:4, 132:11-14, 133:2-12; 134:9-18; Exh. I, Frank Gannon Expert Report, p. 1; Exh. J, Bobst Expert Report, pp. 2-3; Exh. K, Bobst Deposition, pp. 74:13-75:21; Exh. S, Jarrell Report, p. 8, ¶¶13-14)

25. Dr. J.W. Cohen Tervaert, Plaintiffs' treating physician and disclosed expert immunologist, initially examined Jodi Rouviere on April 30, 2019. He reported that Ms. Rouviere

"mentioned that she suffered from fatigue since 2012. The problems started after hip implantation…" (Exh. H, Tervaert Expert Report, p. 3)

26. Dr. Tervaert diagnosed Ms. Rouviere with ASIA (Autoimmune Syndrome Induced by Adjuvants) and opined that her ASIA syndrome was caused by the metal debris from the device components implanted in August 2012. (*Id*., Tervaert Expert Report, pp. 1, 12)

27. Dr. Tervaert testified that he based his causation opinion on Ms Rouviere's reporting of symptoms consistent with ASIA in 2012 after her total hip replacement. He testified at deposition: "[W]hat happened is that in 2012 the hip implants were placed, she started to develop all the symptoms that are compatible with ASIA." (Exh. H, Tervaert Dep., 132:11-14). He also testified: "As mentioned, her ASIA symptoms started in 2012. The trigger can't be in 2016 or 2017." (*Id*. at 133:2-12) He also testified: "When I saw her, she mentioned that it [chronic fatigue] started in 2012…after the hip implant." (*Id*. at 134:9-18)

28. Dr. Sol Bobst, Plaintiffs' expert toxicologist, opined in his expert report, "Exposure to metals from medical device degradation is likely to have begun in 2012 following her first surgery." (Exh. J, Bobst Expert Report, p. 3)

29. In Paragraph 88 of the Amended Complaint, Plaintiffs allege:

> Defendants have long been aware, including before Plaintiff's receipt of her Summit, that Summit Devices may result in metallosis, biologic toxicity, and high failure rate" and that the device components "when implanted, result[] [in] unsafe release of toxic metal particles and ions into hip implant recipients' tissue and bloodstream. Plaintiff further alleges that Defendants were and continue to be aware that the metal particles from Summit Devices results in metallosis, tissue death and bone erosion.
>
> (ECF No. 26, Amended Complaint, ¶88)

30. Plaintiffs allege that HOC was "at all relevant times" aware that the MDM® system "resulted in unsafe release of toxic metal ions into the tissues and bloodstream of the recipients." (*Id*., Amended Complaint, ¶129)

31. Plaintiffs alleged that "[s]tudies published prior to the Plaintiffs implant in 2012 have shown that exposure to Titanium, Aluminum and other metals, hydroxyapatite and other coatings and textures applied can cause severe inflammatory reaction secondary to wear particles and/or host immunological sensitivity." (*Id*., ¶143)

32. Dr. Buly testified to the following at deposition:

- He was aware well before August of 2012 that tissue reactions could be caused by metallic corrosion, allergic reactions, or the accumulation of metal wear debris (Exh. R, Buly Dep., 82:10-22)
- He was aware at the time of the August 2012 implant surgery that reaction to metal wear debris was a known risk in any total hip replacement. (*Id*., 290:20-292:3)
- He was aware in August 2012 that metal debris or metal ions from hip replacement components could lead to adverse tissue reaction and metallosis. (*Id*., 296:16-298:11)

33. Plaintiffs' toxicology expert, Dr. Sol Bobst, opined in his expert report:

> Debris-Mediated Osteolysis is a known issue that includes a spectrum of effects that include bone loss when an implant fails and releases metal debris into the surrounding tissue (**Clarke *et al* 1992**). Experimental studies *in vitro* evaluating the exposure of monocytes to Cobalt-Chromium nanoparticles and cobalt ions resulted in the release of THF-α, a likely mechanism related to the osteolysis (bone loss) in vivo (**Posada *et al* 2015**). This is related to the known metal wear particles found in patients with metal hip replacements (**Doorn *et al* 1998**). The presence of metal ions in blood is also a recognized clinical indication used for evaluating the pathological impact of hip arthroplasty (**Campbell *et al* 2014**). A previous report in the literature of a patient that was implanted with a similar hip implant from the same manufacturer, around the same date and time as Ms. Rouviere, experienced Cobalt levels in the blood (**Kao *et al* 2014**). Neurological symptoms have also been reported as systemic toxicity related to metal hip prostheses and Cobalt (**Bradberry *et al* 2014**). Adverse effects on the immune system responding to the release of debris from hip replacements have also been documented (**Brown *et al* 2005**). Cognitive

> symptoms have also been reported for patients that have received metal-on-metal hip prostheses that contain Cobalt. (**Mao *et al* 2011**). The presence of Cobalt has also been associated with immune response and osteo related pathology (**Queally *et al* 2009, Brock & Stopford 2003, Keegan *et al* 2007, Hart *et al* 2006**)…

(Exh. J, Bobst Expert Report, pp. 2-3)

34. Plaintiffs' biomedical engineering expert, Dr. John Jarrell, opined: "Reactions for metal on metal contact, wear debris and corrosion as it related to hip implants is known and documented in the scientific literature since at least 1975." (Exh. S, Jarrell Expert Report, p. 34)

35. Dr. Jarrell also cited to a 1998 study in support of the following statement in his expert report:

> The risks from metal debris, are however well established in the scientific literature where it states, "As a result of in vitro dissolution tests of metallic materials, Doi et al. also reported that the **amounts of released metallic soluble ions increased with the presence of wear**. These facts indicate that even metallic materials with **high resistance to corrosion possibly corrode inside a body with the presence of wear**. Therefore, it should be better that metallic biomaterials for artificial joints or long term implantations consist of metallic elements having relatively low toxicity, because the toxicity of biomaterials is the toxicity of released ions or debris, and all of the implanted metallic materials release metal ions or debris with the presence of wear (fretting)."

(Exh. S. Jarrell Report, pp. 36-37) (emphasis in original)

Dated: March 18, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was electronically served on the following counsel of record via the Court's electronic filing system on this 18th day of March, 2022:

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